

PATENT COOPERATION TREATY

COPY

PCT

From the
INTERNATIONAL PRELIMINARY EXAMINING AUTHORITY

To:

CASEY, Lindsay J.
F.R. KELLY & CO.
27 Clyde Road
Ballsbridge
Dublin 4
IRLANDE

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL PRELIMINARY
EXAMINATION REPORT
(PCT Rule 71.1)

Date of mailing
(day/month/year) 07.03.2005

Applicant's or agent's file reference
P68878PC00

IMPORTANT NOTIFICATION

International application No.
PCT/B 03/06399

International filing date (day/month/year)
05.12.2003

Priority date (day/month/year)
05.12.2002

Applicant
UNIVERSITY OF ULSTER et al

1. The applicant is hereby notified that this International Preliminary Examining Authority transmits herewith the international preliminary examination report and its annexes, if any, established on the international application.
2. A copy of the report and its annexes, if any, is being transmitted to the International Bureau for communication to all the elected Offices.
3. Where required by any of the elected Offices, the International Bureau will prepare an English translation of the report (but not of any annexes) and will transmit such translation to those Offices.
4. **REMINDER**

The applicant must enter the national phase before each elected Office by performing certain acts (filing translations and paying national fees) within 30 months from the priority date (or later in some Offices) (Article 39(1)) (see also the reminder sent by the International Bureau with Form PCT/IB/301).

Where a translation of the international application must be furnished to an elected Office, that translation must contain a translation of any annexes to the international preliminary examination report. It is the applicant's responsibility to prepare and furnish such translation directly to each elected Office concerned.

For further details on the applicable time limits and requirements of the elected Offices, see Volume II of the PCT Applicant's Guide.

The applicant's attention is drawn to Article 33(5), which provides that the criteria of novelty, inventive step and industrial applicability described in Article 33(2) to (4) merely serve the purposes of international preliminary examination and that "any Contracting State may apply additional or different criteria for the purposes of deciding whether, in that State, the claimed inventions is patentable or not" (see also Article 27(5)). Such additional criteria may relate, for example, to exemptions from patentability, requirements for enabling disclosure, clarity and support for the claims.

RECEIVED

10 MAR 2005

Name and mailing address of the International
preliminary examining authority:



European Patent Office - Gitschiner Str 103
D-10958 Berlin
Tel. +49 30 25901 - 0
Fax: +49 30 25901 - 840

Authorized Officer

Koster, A

Tel +49 30 25901-726

COMPUTER DIARIED
Date:



PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P68878PC00	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/PEA/416)	
International application No. PCT/IB 03/06399	International filing date (<i>day/month/year</i>) 05.12.2003	Priority date (<i>day/month/year</i>) 05.12.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/053		
Applicant UNIVERSITY OF ULSTER et al		

<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 6 sheets, including this cover sheet.</p> <p><input checked="" type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of 9 sheets.</p>
--

<p>3 This report contains indications relating to the following items:</p> <ul style="list-style-type: none"> I <input checked="" type="checkbox"/> Basis of the opinion II <input type="checkbox"/> Priority III <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability IV <input type="checkbox"/> Lack of unity of invention V <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement VI <input type="checkbox"/> Certain documents cited VII <input type="checkbox"/> Certain defects in the international application VIII <input type="checkbox"/> Certain observations on the international application

Date of submission of the demand 05.07.2004	Date of completion of this report 07.03.2005
Name and mailing address of the International preliminary examining authority: <div style="display: flex; align-items: center;"> <div> European Patent Office - Gilschiner Str. 103 D-10958 Berlin Tel. +49 30 25901 - 0 Fax: +49 30 25901 - 840 </div> </div>	Authorized Officer Trachterna, M Telephone No. +49 30 25901-592



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB 03/06399

I. Basis of the report

1. With regard to the elements of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, Pages

1-14 as originally filed

Claims, Numbers

1-29 received on 21.02.2005 with letter of 15.02.2005

Drawings, Sheets

1/5-5/5 as originally filed

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
☐ the language of publication of the international application (under Rule 48.3(b)).
☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
☐ filed together with the international application in computer readable form.
☐ furnished subsequently to this Authority in written form.
☐ furnished subsequently to this Authority in computer readable form.
☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
☐ the claims, Nos.:
☐ the drawings, sheets:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/IB 03/06399

5. ☒ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

see separate sheet

6. Additional observations, if necessary:

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	1-26
	No: Claims	
Inventive step (IS)	Yes: Claims	17,26
	No: Claims	1-16,18-25
Industrial applicability (IA)	Yes: Claims	1-26
	No: Claims	

2. Citations and explanations

see separate sheet

Re Item I

Basis of the report

The amendments filed with the letter dated 15.02.2005 introduce subject-matter which extends beyond the content of the application as filed, contrary to Article 34(2)(b) PCT. The amendments concerned are the following:

- means for presenting at least one value representing a physical characteristic of at least one region of tissue.

The disclosure of the present application (see p. 13/l. 5-9) is limited to the presentation of area and ratio calculated on measured impedance values. Neither the claims nor the description (see in particular p. 7/l. 20-26) as originally filed support the above broadening of independent claims 1, 20.

Further the applicant has broadened the scope of protection by replacing the "tissue mapping" system or method by a "tissue measurement" system or method (see claims 1, 20).

These amendments introduce subject-matter which extends beyond the content of the application as filed. Consequently, the reasoned statement with regard to novelty, inventive step and industrial applicability has been established on the basis of claims 1-26 filed with the letter dated 01.12.2004.

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

- D1: LACKERMEIER A H ET AL: "IN VIVO AC IMPEDANCE SPECTROSCOPY OF HUMAN SKIN THEORY AND PROBLEMS IN MONITORING OF PASSIVE PERCUTANEOUS DRUG DELIVERY" ANNALS OF THE NEW YORK ACADEMY OF SCIENCES, NEW YORK ACADEMY OF SCIENCES, NEW YORK, NY, US, vol. 873, 20 April 1999, pages 197-213, XP008029774 ISSN:

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/IB 03/06399

0077-8923

D2: US 2002/082668 A1 (INGMAN DOV) 27 June 2002

D3: US-A-5 184 620 (CUDAHY MICHAEL J ET AL) 9 February 1993

1. The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-16, 18-25 does not involve an inventive step in the sense of Article 33(3) PCT.
 - 1.1 The document D3 is regarded as being the closest prior art to the subject-matter of claim 1, and discloses (the references in parentheses applying to this document): a tissue mapping system comprising (col. 6/l. 32-33):
 - a two dimensional array of test electrodes (col. 5/l. 45-47, fig. 1(12))) for application to the surface of tissue under investigation; and
 - circuit means (col. 6/l. 24-30, fig. 1(36)) for measuring an electrical characteristic of the tissue underlying each test electrode;

The subject-matter of claim 1 therefore differs from this known mapping system of D1 in that: a display device provides a visual map of the tissue based upon the measured electrical characteristics.

The problem to be solved by the present invention may therefore be regarded as how to provide a visual representation of the measured electrical characteristics.

However, the skilled person would regard it as a normal option to connect the mapping system of D1 which is adapted to be connected to external diagnostic or monitoring devices (col. 6/l. 22-24) to a display device providing a visual map of the tissue based upon the measured electrical characteristics. Therefore, the solution proposed in claim 1 of the present application does not involve an inventive step (Article 33(3) PCT).

- 1.2 The same reasoning applies, mutatis mutandis, to the subject-matter of the corresponding independent claim 18, which therefore is also considered not inventive.
 - 1.3 Dependent claims 2-16, 19-25 do not contain any features which, in combination with

the features of any claim to which they refer, meet the requirements of the PCT in respect of inventive step, see document D1, D3 and the corresponding passages cited in the search report.

2. The combination of the features of dependent claims 17, 26 is neither known from, nor rendered obvious by, the available prior art. The reasons are as follows:

The subject-matter of claims 17, 26 is new (Article 33(2) PCT) (see 1.1 and 1.2 above).

The problem to be solved by the present invention may be regarded as how to monitor the progression of wound healing. In order to solve the problem the array of test electrodes is incorporated into a wound dressing. Since no indication nor even a hint has been found in the available prior art, which would have caused the skilled person to extend the known mapping system of D1 by the incorporation of the array of test electrodes into a wound dressing, the subject-matter of dependent claims 17, 26 is considered as involving an inventive step (Article 33(3) PCT).

3. The industrial applicability (Art. 33(4) PCT) is clearly given for the subject-matter of all apparatus claims. However, it is noted that no unified criteria exists as regards industrial applicability of diagnostic methods. If the method claims are maintained, this issue will therefore be the subject of further examination in a later regional/national phase.

Claims

1. A tissue measurement system comprising a two-dimensional array of test electrodes for application
5 to the surface of tissue under investigation, circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and means for presenting at least one value representing a physical characteristic of at
10 least one region of tissue based upon the measured electrical characteristics.
2. A system as claimed in claim 1, wherein the physical characteristic is area.
- 15 3. A system as claimed in claim 2, wherein the presenting means presents a plurality of values on a display device to provide a visual map representing the physical extent of the region of tissue.
- 20 4. A system as claimed in claim 1, 2 or 3, wherein the array of test electrodes is arranged on a flexible backing of insulating material.
- 25 5. A system as claimed in claim 4, wherein the array of electrodes is a rectangular array.
6. A system as claimed in claim 4 or 5, wherein each
30 test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.

7. A system as claimed in claim 6, wherein the gel is hydrogel.
8. A system as claimed in any one of claims 4 to 7,
5 wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.
9. A system as claimed in any preceding claim, wherein
10 the two-dimensional array comprises at least 25 test electrodes.
10. A system as claimed in any preceding claim, wherein
15 the electrical characteristic is the impedance of the tissue underlying each test electrode.
11. A system as claimed in any preceding claim, wherein
the circuit means measures the electrical
characteristic by applying an alternating electrical
20 signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.
12. A system as claimed in claim 11, wherein the circuit
25 means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.
- 30 13. A system as claimed in claim 12, wherein the reference electrode is also disposed on the flexible backing of insulating material.

14. A system as claimed in claim 13, wherein a single reference electrode is common to a plurality of test electrodes.
- 5 15. A system as claimed in claim 13, wherein during measurement on a given test electrode an adjacent test electrode acts temporarily as its reference electrode.
- 10 16. A system as claimed in any one of claims 11 to 15, wherein the said at least one other electrode is also disposed on the flexible backing of insulating material.
- 15 17. A system as claimed in any one of claims 11 to 16, wherein for each test electrode a measurement is made at a plurality of different frequencies.
18. A system as claimed in any one of claims 11 to 17,
20 wherein the or each measurement is made at a frequency of from 1 milliHz to 100 kHz, preferably from 1 Hz to 50 kHz.
19. A system as claimed in any preceding claim, wherein
25 the array of test electrodes is incorporated into a wound dressing.
20. A method of measuring tissue comprising applying a two-dimensional array of test electrodes to the
30 surface of tissue under investigation, measuring an electrical characteristic of the tissue underlying each test electrode, and presenting at least one value representing a physical characteristic of at

least one region of tissue based upon the measured electrical characteristics.

21. A method as claimed in claim 20, wherein the
5 physical characteristic is area.
22. A method as claimed in claim 21, wherein a
plurality of values are presented on a display
device to provide a visual map representing the
10 physical extent of the region of tissue.
22. A method as claimed in claim 20, 21 or 22, wherein
the array of test electrodes is arranged on a
flexible backing of insulating material.
15
23. A method as claimed in claim 22, wherein each test
electrode is covered with a conductive gel, the
resistance between adjacent test electrodes being
high relative to the resistance via the gel between
20 each test electrode and the underlying tissue.
24. A method as claimed in any one of claims 20 to 23,
wherein the two-dimensional array comprises at least
25 test electrodes.
25. A method as claimed in any one of claims 20 to 24,
wherein the electrical characteristic is the
impedance of the tissue underlying each test
electrode.
30
26. A method as claimed in any one of claims 20 to 25,
wherein the electrical characteristic is measured by
applying an alternating electrical signal between
the test electrode and at least one other electrode

applied to the organic body of which the tissue forms a part.

27. A method as claimed in claim 26, wherein the
5 electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.
- 10 28. A method as claimed in claim 26 or 27, wherein for each test electrode a measurement is made at a plurality of different frequencies.
- 15 29. A method as claimed in any one of claims 20 to 28, wherein the array of test electrodes is incorporated into a wound dressing and applied to a wound.

Claims

1. A tissue mapping system comprising a two-dimensional array of test electrodes for application
5 to the surface of tissue under investigation, circuit means for measuring an electrical characteristic of the tissue underlying each test electrode, and a display device providing a visual map of the tissue based upon the measured electrical
10 characteristics.
2. A system as claimed in claim 1, wherein the array of test electrodes is arranged on a flexible backing of insulating material.
15
3. A system as claimed in claim 2, wherein the array of electrodes is a rectangular array.
4. A system as claimed in claim 2 or 3, wherein each
20 test electrode is covered with a conductive gel, the resistance between adjacent test electrodes being high relative to the resistance via the gel between each test electrode and the underlying tissue.
- 25 5. A system as claimed in claim 4, wherein the gel is hydrogel.
6. A system as claimed in any one of claims 2 to 5,
30 wherein leads for the test electrodes are also disposed on the flexible backing of insulating material and covered with an insulating material.

7. A system as claimed in any preceding claim, wherein the two-dimensional array comprises at least 25 test electrodes.
- 5 8. A system as claimed in any preceding claim, wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.
9. A system as claimed in any preceding claim, wherein
10 the circuit means measures the electrical characteristic by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.
- 15 10. A system as claimed in claim 9, wherein the circuit means measures the electrical characteristic by measuring the voltage between each test electrode and an adjacent reference electrode also applied to
20 the tissue.
11. A system as claimed in claim 10, wherein the reference electrode is also disposed on the flexible backing of insulating material.
- 25 12. A system as claimed in claim 11, wherein a single reference electrode is common to a plurality of test electrodes.
- 30 13. A system as claimed in claim 11, wherein during measurement on a given test electrode an adjacent test electrode acts temporarily as its reference electrode.

14. A system as claimed in any one of claims 9 to 13,
wherein the said at least one other electrode is
also disposed on the flexible backing of insulating
material.
- 5
15. A system as claimed in any one of claims 9 to 14,
wherein for each test electrode a measurement is
made at a plurality of different frequencies.
- 10
16. A system as claimed in any one of claims 9 to 15,
wherein the or each measurement is made at a
frequency of from 1 milliHz to 100 kHz, preferably
from 1 Hz to 50 kHz.
- 15
17. A system as claimed in any preceding claim, wherein
the array of test electrodes is incorporated into a
wound dressing.
18. A method of mapping tissue comprising applying a
two-dimensional array of test electrodes to the
surface of tissue under investigation, measuring an
electrical characteristic of the tissue underlying
each test electrode, and displaying a visual map of
the tissue based upon the measured electrical
characteristics.
- 20
- 25
19. A method as claimed in claim 18, wherein the array
of test electrodes is arranged on a flexible backing
of insulating material.
- 30
20. A method as claimed in claim 19, wherein each test
electrode is covered with a conductive gel, the
resistance between adjacent test electrodes being

high relative to the resistance via the gel between each test electrode and the underlying tissue.

21. A method as claimed in any one of claims 18 to 20,
5 wherein the two-dimensional array comprises at least 25 test electrodes.
22. A method as claimed in any one of claims 18 to 21,
10 wherein the electrical characteristic is the impedance of the tissue underlying each test electrode.
23. A method as claimed in any one of claims 18 to 22,
15 wherein the electrical characteristic is measured by applying an alternating electrical signal between the test electrode and at least one other electrode applied to the organic body of which the tissue forms a part.
- 20 24. A method as claimed in claim 23, wherein the electrical characteristic is measured by measuring the voltage between each test electrode and an adjacent reference electrode also applied to the tissue.
- 25 25. A method as claimed in claim 23 or 24, wherein for each test electrode a measurement is made at a plurality of different frequencies.
- 30 26. A method as claimed in any one of claims 18 to 25, wherein the array of test electrodes is incorporated into a wound dressing and applied to a wound.